UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
BEAUMONT DIVISION

JUDY ROMERO,	§	
	§	
Plaintiff,	§	Civil Action No. 1:03-CV-01367-MAC
	§	
vs.	§	
	§	
WYETH LLC,	§	Honorable Marcia A. Crone
	§	
Defendant.	§	

WYETH'S MOTION FOR PARTIAL SUMMARY JUDGMENT AND BRIEF IN SUPPORT

Pursuant to Federal Rule of Civil Procedure 56, Wyeth LLC f/k/a Wyeth, Inc. and Wyeth Pharmaceuticals, Inc. ("Wyeth") moves for summary judgment on Plaintiff Judy Romero's claims based on an alleged failure to warn and her claims of strict liability: design defect, and negligent design – and urges that Ms. Romero cannot recover either actual or exemplary damages under any theory. Wyeth respectfully shows the Court the following:

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I. SUMMARY

Critical to this Court's analysis is the statutory presumption of non-liability that is found in Texas Civil Practice & Remedies Code § 82.007. The presumption applies when the medications at issue, like the hormone therapy ("HT") in this case, have the approval of the U.S. Food & Drug Administration ("FDA"). There are a number of statutory exceptions to the presumption, including a "fraud-on-the-FDA" exception. But the Fifth Circuit's recent decision in *Lofton v. McNeil Consumer & Specialty Pharmaceuticals*, Case No. 10-10956, Feb. 22, 2012 ("*Lofton* Opinion") (attached as **Exhibit 1**), forecloses any argument that the statutory fraud-on-the-FDA exception to the presumption applies. According to the Fifth Circuit, "federal law preempts a Texas tort reform law that requires plaintiffs to assert, in failure to warn cases, that a drug manufacturer withheld or misrepresented material information to the FDA." *Id.* at 2. None of the other statutory exceptions to the presumption of non-liability apply in this case, and therefore, the presumption is dispositive of all of Ms. Romero's claims based on an alleged failure to warn.

Wyeth is also entitled to summary judgment on Ms. Romero's claims for design defect and negligent design because, under Section 402A of the Restatement (Second) of Torts, design defect is not an appropriate claim in a case involving prescription drugs. Furthermore, there is no competent evidence of any safer alternative design, which is a requisite of any design defect or negligent design claim. Finally, there is no basis for the recovery of exemplary damages under any theory.[1]

[1] Wyeth acknowledges the Court's order granting in part and denying part a motion for summary judgment in *Lea v. Wyeth LLC, et al.*, Cause No. 1:03-cv-01339-mac. Wyeth does not intend to rehash issues that the Court has previously addressed. However, the Court issued its opinion in *Lea* prior to the Fifth Circuit's ruling in *Lofton*. In addition, some of the issues raised in *Lea* again warrant consideration in this matter. Wyeth, therefore, has limited this Motion for Summary Judgment to those issues. In addition, pursuant to a stipulation of the parties, this Court has dismissed Ms. Romero's claims for assault and battery, breach of express warranty, breach of implied warranty, negligence *per se*, and manufacturing defect. *See* Order [Dkt. No. 78, dated Feb. 22, 2012].

II. STATEMENT OF ISSUES

1. Plaintiff's First Amended Petition [sic] includes several claims based on an alleged theory of failure-to-warn. There is no dispute that the medications at issue were approved by the FDA, and therefore, the statutory presumption of non-liability found in § 82.007 of the Civil Practice & Remedies Code applies. Given that the fraud-on-the-FDA exception to the presumption of non-liability is preempted, does Ms. Romero have sufficient evidence to establish any of the other statutory exceptions to the presumption of non-liability?

2. Are Ms. Romero's claims for design defect and negligent design barred by Section 402A of the Restatement (Second) of Torts, which prohibits the assertion of design defect claims for prescription drugs?

3. Does Ms. Romero have sufficient evidence of the existence of a safer alternative design when she has no evidence that any safer alternative design was feasible at the time she was taking HT; that her doctors would have prescribed any safer alternative design for the treatment of her menopausal symptoms or that it would have been effective in treating her symptoms; and that any safer alternative design would have prevented her breast cancer?

4. Is there sufficient evidence of malice, fraud, or gross negligence to justify an award of punitive damages?

III. STATEMENT OF UNDISPUTED MATERIAL FACTS

A. Background Facts Related to HT

FDA-approved HT medicines are indicated for the treatment of menopausal symptoms and the prevention of osteoporosis.[2] Since 1942, when Wyeth first introduced HT to the market, until the present day, doctors have prescribed such medicines to menopausal women.[3] In 1994 the FDA approved Prempro, a combination of conjugated equine estrogen and medroxyprogesterone acetate (progestin).[4] In approving Prempro and its labeling, the FDA necessarily determined that Wyeth's NDA "include[ed] adequate tests by all methods reasonably applicable." 21 U.S.C. § 355(d)(1).

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[2] **Exhibit 2 -** Opinion, *Bailey v. Wyeth, Inc.*, No. MID-L-0999-06-MT (N.J. Super. Ct., Middlesex County July 11, 2008) ("Bailey Opinion") (discussing the FDA approval of Premarin, Provera, and Prempro).

[3] *Id.* (noting that Premarin and Prempro are still on the market today and approved by the FDA for the treatment of menopausal symptoms and that Provera continues to be approved by the FDA).

[4] *Id.* (discussing the FDA approval of HT medications).

Premphase also contains both estrogen and progestin and is the cyclical version of Prempro.[5] These medications are still approved by the FDA and on the market today.[6]

Prior to the approval of Prempro, the FDA convened an independent Advisory Committee, which met in 1990 and 1991 to analyze the science on HT.[7] An FDA advisory committee is an independent "technical and scientific review group[]," 21 U.S.C. § 393(e), that is "designed to assure that its advice and recommendations are the result of the advisory committee's independent judgment." 21 C.F.R. § 14.40(f)(3). Members of the committee must "have diverse professional education, training, and experience so that the committee will reflect a balanced composition of sufficient scientific expertise," 21 C.F.R. § 14.80(b)(1)(i), and to enable them "to evaluate the safety and effectiveness of the drugs . . . referred to the panel." 21 U.S.C. § 355(n)(3)(A).

Wyeth sent the FDA an exhaustive review of the world's literature published since 1976 examining the possible relationship between breast cancer and hormone replacement therapy.[8] The advisory committee reviewed this information and heard testimony from independent experts.[9] In 1990, the committee unanimously found that the information regarding an increased risk of breast cancer was not conclusive.[10] In 1991, it concluded that it "had enough information about the benefits that the small unknown risk was reasonable to accept" and that it would "consider approving specific NDAs for combined hormone therapy."[11]

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5 **Exhibit 17** - Premphase Package Insert (dated Nov. 10, 1995).
6 **Exhibit 2** - *Bailey* Opinion at 17.
7 **Exhibit 18** - Excerpts from the *Daniel v. Wyeth* Trial Testimony of Dr. Lisa Rarick (Jan. 24, 2007) A.M. Session at 56:12-57:22.
8 *Id.* at 59:22-60:3
9 *Id.* at 59:6-61:19.
10 *Id.* at 61:11-62:2.
11 *Id.* at 62:11-16, 65:10-18, 66:6-67:4.

In the 1990s, the National Institutes of Health ("NIH") undertook a massive randomized clinical trial[12] called the Women's Health Initiative ("WHI") to evaluate the risks and benefits of numerous women-specific medications and treatments, including Prempro. This study was one of the largest randomized clinical trials ever done to study the health of post-menopausal women.[13] The Prempro portion of the study evaluated more than 16,000 women for more than five years, with approximately half receiving Prempro and the other half receiving a placebo.[14] The medical and scientific communities recognized this large, randomized, controlled clinical trial as the "gold standard" of medical evidence and as providing the best data regarding the benefits and risks of Prempro in post-menopausal women.[15] The WHI investigators reported that women taking Prempro every day for approximately five years had a slightly higher risk of being diagnosed with breast cancer compared to women taking placebo pills.[16] They also reported that Prempro conferred no increased risk of breast cancer if taken by post-menopausal women for less than five years.[17] More than 97% of women who

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[12] A randomized clinical trial is a study where "the participants are assigned by chance to separate groups that compare different treatments . . . ." *See* Nat'l Cancer Institute, Definition of Cancer Terms, http://www.cancer.gov/dictionary?cdrid=45858 (last visited Jan. 9, 2012). No one can choose which group each participant will belong to, and the use of randomized groups allows for objective comparisons. *Id.*

[13] *The Women's Health Initiative Participant Website: About WHI*, WHI.org, http://www.whi.org/about/whi.php (last visited Feb. 9, 2012).

[14] **Exhibit 9** - *Chlebowski et al., Influence of Estrogen Plus Progestin on Breast Cancer and Mammography in Healthy Postmenopausal Women*, 289 J. AM. MED. ASS'N 3243, 3244 (2003) ("Chlebowski 2003").

[15] The WHI results were important because the medical community considers clinical trials to be the most reliable form of scientific evidence, and far superior to observational studies. Green et al., *Reference Guide on Epidemiology*, *in* REFERENCE MANUAL ON SCIENTIFIC EVIDENCE 333, 338 (2d ed. 2000) ("Reference Manual"); **Exhibit 6** - *Hulley et al.*, DESIGNING CLINICAL RESEARCH 157–58, 195 (3d ed. 2007); **Exhibit 7** - Piantadosi et al., *Larger Lessons from Women's Health Initiative*, 14 EPIDEMIOLOGY 6, 6-7 (2003); **Exhibit 8** - Herrington & Howard, *From Presumed Benefit to Potential Harm – Hormone Therapy and Heart Disease*, 349 N. ENGL. J. MED. 519, 519 (2003).

[16] WHI reported a relative risk of 1.24 (or 24%) for breast cancer in women taking Prempro. **Exhibit 9** - Chlebowski 2003 at 3243; **Exhibit 10** - FDA Physician's Desk Reference, Feb. 2010 ("Prempro 2010 PDR").

[17] **Exhibit 9** - Chlebowski 2003 at 3248, tbl.2.

took Prempro in the study did not develop breast cancer.[18] The study also showed that women taking Prempro did not have an increased risk of being diagnosed with Ms. Romero's type of tumor – ductal carcinoma in situ (DCIS), estrogen receptor positive.[19]

B. Background Facts Related to Ms. Romero

Ms. Romero began experiencing menopausal symptoms in 1996 at the age of 48.[20] Her menopausal symptoms included irregular periods and hot flashes.[21] On October 24, 1996, Dr. Radha J. Lal discussed estrogen replacement therapy with Ms. Romero, and on December 31, 1996, Dr. Lal initiated Premphase.[22] On June 8, 1998, while still taking Premphase, Ms. Romero complained of additional menopausal symptoms including heart irregularities, continued hot flashes, and difficulty sleeping.[23] Ms. Romero continued taking Premphase until February 22, 2000, when Dr. Eberhard Loetze switched her to Prempro.[24]

After Ms. Romero's February 27, 2001 mammogram revealed an area of calcifications in the left breast and a questionable mass in her right breast, she was referred to a surgeon.[25] Dr. Karl Tomm performed a left breast biopsy after needle localization and a right breast biopsy on March 9, 2001.[26]

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18 **Exhibit 9** - Chlebowski 2003 at 3243. 2.3% of women taking Prempro developed invasive breast cancer, compared to 1.9% of women taking placebo. *Id.* at 3250, tbl.4.

19 *See* **Exhibit 9** - Chlebowski 2003 at 3248, 3250.

20 **Exhibit 19** - (excerpts of Judy Romero's medical records), JRomero-O&GA-Houston-000178-JRomero-O&GA-Houston-000179; JRomero-SHE-MD=000035; **Exhibit 22** - (Oral Deposition of Judy Romero (May 22, 2009) at 184:24-185:11, 185:20-186:14 ("Romero Dep.").

21 **Exhibit 19** - (excerpts of Judy Romero's medical records), JRomero-O&GA-Houston-000178-JRomero-O&GA-Houston-000179; JRomero-SEH-MD=000035; **Exhibit 22** - Romero Dep. at 222:12-223:9.

22 **Exhibit 19** - excerpts from Judy Romero's medical records), JRomero-O&GA-Houston-000179; **Exhibit 22** - Romero Dep. at 159:13-16, 239:1-5.

23 **Exhibit 19** - (excerpts from Judy Romero's medical records), JRomero-O&GA-Houston-000026; **Exhibit 22** - Romero Dep. at 222:12-223:9.

24 **Exhibit 19** - (excerpts from Judy Romero's medical records), JRomero-O&GA-Houston-000022.

25 **Exhibit 19** - (excerpts from Judy Romero's medical records), JRomero-KETomm-000057-JRomero-KETomm00058.

26 **Exhibit 19** - (excerpts from Judy Romero's medical records), JRomero-KETomm000031-JRomero-KETomm000032.

The pathology revealed that Ms. Romero had high grade ductal carcinoma in the left breast.[27] No receptor testing was done at that time, but according to Ms. Romero's pathologist, Dr. James Waldron, the tumor was ER+, PR-, and "probably" Her2/neu positive.[28]

Ms. Romero received radiation treatment to the left breast and she began taking Tamoxifen, an estrogen blocker.[29] She has had no evidence of recurrence and her prognosis is good.[30] Prior to her cancer diagnosis, Ms. Romero had a number of risk factors including use of oral contraceptives, lack of breastfeeding, naturally dense breasts, and a family history of cancer.[31]

Ms. Romero did not recall seeing any posters, pamphlets or other advertisements for HT before or during the time she took Premphase and Prempro.[32] Rather, her decision to start and continue using HT was based on her doctor's prescriptions of it to her.[33] Ms. Romero also does not recall any discussions with her prescribers – Dr. Lal and Dr. Lotze – regarding the risks of HT.[34] In addition, she did not recall seeing a patient insert for Premphase and does not know if she read it.[35] She does recall seeing one for Prempro, but she did not read it thoroughly.[36] Ms. Romero stated that she typically "glances" at the sections discussing dosages and side effects, but does not read the entire document.[37]

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27 **Exhibit 19** - (excerpts from Judy Romero's medical records), JRomero-WHT-000020-JRomero-WHT-000021.

28 **Exhibit 21** - Excerpts from the Report of James Waldron at 1.

29 **Exhibit 19** - (excerpts from Judy Romero's medical records), JRomero-KETomm000016, JRomero-KETomm000046-JRomero-KETomm000048; JRomero-TexasOnc-000039-KRomero-TexasOnc-000040.

30 **Exhibit 23** - Excerpts from the Oral Deposition of Scott McKenney, M.D. (Apr. 7, 2011) at 33:9-21.

31 **Exhibit 20** - June 20, 2011 Report of Pamela M. Otto, M.D., FACR at 1-2.

32 **Exhibit 22** - Romero Dep. at 233:12-236:4, 247:19-248:13, 250:2-7, 252:20-253:4.

33 *Id.* at 235:17-236:4.

34 *Id.* at 237:17-238:7, 243:24-244:17, 269:21-270:12.

35 *Id.* at 240:2-12.

36 *Id.* at 253:22-254:13, 266:4-267:17.

37 *Id.* at 266:24-267:17. Ms. Romero also stated that she only briefly looks at any materials provided by the pharmacy. *Id.* at 132:9-134:11, 138:1-17

Ms. Romero's first HT prescriber – Dr. Radha Lal – was familiar with the HT regimen and during the time she saw Ms. Romero, Dr. Lal discussed the pros and cons of HT with her patients.[38] In the mid-1990s Dr. Lal was aware that there was a risk of breast cancer for patients using HT and she counseled patients regarding that risk.[39] Her practice was to give her patients a pamphlet entitled "Hormone Replacement Therapy and Your Health," and she is confident that she gave this pamphlet to Ms. Romero.[40] The pamphlet specifically discussed the risks of breast cancer associated with the use of HT.[41] Whenever she prescribed HT, Dr. Lal followed the patient closely to ensure they were not having any problems.[42] This included pap smears, breast exams, and other routine tests.[43]

Ms. Romero's second prescriber – Dr. Eberhard Lotze – was also aware of the risk of breast cancer associated with HT, although he believed the studies to be inconclusive.[44] Dr. Lotze stayed informed regarding HT by consulting the Physicians' Desk Reference, attending seminars and conferences, and consulting with colleagues and medical journals.[45] He did not pay much attention to sales representatives at all.[46]

It addition to the fact that each of her prescribers was aware of a possible increased risk of breast cancer, it is undisputed that at the time Ms. Romero was prescribed Premphase and Prempro, the package inserts specifically warned of the risk of breast cancer:[47]

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38 **Exhibit 24** - Oral Deposition of Radha J. Lal, M.D. (Apr. 27, 2011) at 38:7-39:24 ("Lal Dep.").
39 *Id.* at 115:18-118:9.
40 *Id.* at 98:3-100:13, Exhibit 3 to the Deposition.
41 *Id.* at 101:21-102:7, 115:18-119:17, 120:23-121:5, Exhibit 3 to the Deposition at p. 11.
42 *Id.*
43 *Id.* at 121:6-123:6.
44 **Exhibit 25** - Oral Deposition of Eberhard C. Lotze, M.D. (Apr. 26, 2011) at 132:10-22 ("Lotze Dep.").
45 *Id.* at 37:15-38:4.
46 *Id.* at 37:23-38:4, 108:6-12, 114:22-115:4, 118:3-8, 248:1-9, 257:12-258:1.
47 **Exhibit 17** - Prempro Package Insert (dated Feb. 10, 1995), Premphase Package Insert (dated Nov. 10, 1995) at 2.

> *Cancer of the breast*. Most studies have not shown a higher risk of breast cancer in women who have ever used estrogens. However, some studies have reported that breast cancer developed more often (up to twice the usual rate) in women who used estrogens for long periods of time (especially more than 10 years), or who used high doses for shorter time periods. The effects of added progestin on the risk of breast cancer are unknown. Some studies have reported a somewhat increased risk, even higher than the possible risk associated with estrogens alone. Others have not. Regular breast examinations by a health professional and monthly self-examination are recommended for all women. Regular mammograms are recommended for all women over 50 years of age.

The Prempro labeling, under "Warnings," also listed "Induction of malignant neoplasms" with specific reference to breast cancer.[48] In addition, the Prempro labeling, under "Contraindications," identified "[k]nown or suspected cancer of the breast"; under "Precautions," referred to "epidemiologic evidence suggest[ing] that progestins do not reduce, and may enhance the moderately increased breast cancer risk that has been reported with prolonged estrogen replacement therapy"; and under "Mutagenesis and Carcinogenesis," said that, in animal testing, the long-term use of estrogen increases the frequency of "carcinomas of the breasts."[49]

The Prempro patient-information sheet, which came in the sealed packet containing each month's supply of pills, did so under the heading "Risks of Estrogens and/or Progestins."[50] Under the caution, "Be alert for signs of trouble," the Prempro sheet listed "Breast lumps (possible breast cancer . . .)."[51] Under "Who Should Not Use Estrogens," the sheet further advised that "[s]ince estrogens increase the risk of certain types of cancer," a woman should not use Prempro if she has had breast

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48 **Exhibit 17** - 1999 Physicians' Desk Reference for Prempro.

49 *Id.*

50 **Exhibit 17** - Prempro Package Insert (dated Feb. 10, 1995).

51 *Id.* *See also* **Exhibit 17** - Premphase Package Insert (dated Nov. 10, 1995) at 2 (warning that women should be alert for breast lumps, which could indicate possible breast cancer), Premphase Package Insert (dated May 21, 1997).

cancer.[52] Finally, the sheet warned that "[a]dditional risks include a possible further increase in breast cancer risk which may be associated with long-term estrogen use."[53]

IV. SUMMARY JUDGMENT STANDARD

Summary judgment is proper when it appears from the record "that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." FED. R. CIV. P. 56(c). The movant must identify those portions of the pleadings or other evidence that demonstrate the absence of a genuine issue of material fact. *See Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986); *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247-48 (1986). Once a proper motion has been made, the nonmoving party must present affirmative evidence, setting forth specific facts, to show the existence of a genuine issue for trial. *See Celotex Corp.*, 477 U.S. at 322-23; *Anderson*, 477 U.S. at 247-48. "Summary judgment is mandated if the nonmovant fails to make a showing sufficient to establish the existence of an element essential to her case on which he bears the burden of proof at trial." *Finnicum v. Wyeth*, 708 F. Supp. 2d 616, 619 (E.D. Tex. 2010) (internal citation omitted).

V. ARGUMENT AND AUTHORITIES

A. Ms. Romero Cannot Recover for Failure to Warn Whether the Legal Theory is Strict Liability, Negligence or Misrepresentation, Fraud, and Deceit.

Texas law affords a statutory presumption that pharmaceutical manufacturers are not liable for warnings that have FDA approval. TEX. CIV. PRAC. & REM. CODE ANN. § 82.007 (Vernon 2011). Ms. Romero bears the burden to establish one of the statutory exceptions to § 82.007. Under the Fifth Circuit's decision in *Lofton v. McNeil Consumer & Specialty Pharmaceuticals*, the fraud-on-the-FDA exception is preempted unless the FDA itself finds fraud. **Exhibit 1** - *Lofton* Opinion. There is no

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[52] **Exhibit 17** - Prempro Package Insert (dated Feb. 10, 1995). *See also* **Exhibit 17** - Premphase Package Insert (dated Nov. 10, 1995) at 1 (warning that women who have had breast cancer should not use Premphase).

evidence of any such finding by the FDA with respect to Premphase and Prempro, and there is no competent evidence indicating that any of the other statutory exceptions apply. Thus, the statutory presumption of non-liability is dispositive of every cause of action based on the alleged failure to warn. In addition, should the Court preclude Ms. Romero's regulatory experts from offering their failure-to-test opinions in this case,[54] it also should grant summary judgment on Ms. Romero's failure-to-warn claims for the additional reason that her failure-to-warn claims require admissible expert testimony supporting the failure-to-test theory.

1. **Texas Law Presumes Non-Liability in Failure-to-Warn Cases.**

It is undisputed that Premphase and Prempro, together with their labeled warnings, were reviewed and approved by the FDA.[55] In these circumstances, § 82.007 affords a statutory presumption that the manufacturer is not liable for failing to provide an adequate warning. *See Lofton v. McNeil Consumer & Specialty Pharms.*, 682 F. Supp. 2d 662, 675-76 (N.D. Tex. 2010) (dismissing plaintiffs' claims premised on failure to warn when the statutory presumption of adequacy was not rebutted). Specifically, the statute provides that

> In a products liability action alleging that an injury was caused by a failure to provide adequate warnings or information with regard to a pharmaceutical product, *there is a rebuttable presumption that the defendant or defendants, including a health care provider, manufacturer, distributor, and prescriber, are not liable with respect to the allegations involving failure to provide adequate warnings or information if* the warnings or information that accompanied the product in its distribution were those approved by the [FDA.]

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53 **Exhibit 17** - Prempro Package Insert (dated Feb. 10, 1995). *See also* **Exhibit 17** - Premphase Package Insert (dated Nov. 10, 1995) at 2 ("Additional risks include a possible further increase in breast cancer risk which may be associated with long-term estrogen use.").

54 *See* Defendants' Motion to Exclude the Testimony of Drs. Parisian, Blume, and Patsner, which is being filed contemporaneously with this Motion and is incorporated herein by reference.

55 *See supra* note 2.

§ 82.007(a) (emphasis added). The statutory presumption in subsection (a)(1) applies here because (1) this is a products liability action alleging injury caused by a failure to provide adequate warnings and (2) it is undisputed that FDA approved the HT warnings at issue in this lawsuit.

Section 82.007 (b) contains the following statutory exceptions:

(1) during the approval process the defendant withheld or misrepresented information to the FDA that was material and relevant to the performance of the product and was causally related to the claimant's injury;

(2) the pharmaceutical product was sold or prescribed in the U.S. after an order of the FDA to remove the product from the market or withdraw its approval of the product;

(3) the defendant recommended, promoted, or advertised the pharmaceutical product for an indication not approved by the FDA; the product was used as recommended, promoted, or advertised; and the claimant's injury was causally related to the recommended, promoted, or advertised use of the product;

(4) the defendant prescribed the pharmaceutical product for an indication not approved by the FDA; the product was used as prescribed; and the claimant's injury was causally related to the prescribed use of the product; and

(5) before or after pre-market approval or licensing of the product the defendant engaged in conduct in violation of 18 U.S.C. § 201 and that conduct caused the approved warnings or instructions for the product to be inadequate

TEX. CIV. PRAC. & REM. CODE ANN. § 82.007(b) (Vernon 2011).

To overcome the statutory presumption, Ms. Romero must ***establish*** one of the exceptions. This requires more than just presenting "some" evidence of one of the exceptions. **Exhibit 1** - *Lofton* Opinion at p. 9 (noting that the fraud-on-the-FDA exception is "a requirement to *prove* fraud on the FDA") (emphasis added).[56] Ms. Romero cannot establish any of the five exceptions in this case.[57]

[56] *See also Trevino v. Ortega*, 969 S.W.2d 950, 960 (Tex. 1998) (Baker, J., concurring) (discussing "Morgan-type" presumptions as those that require the opponent to disprove the presumed facts); *Wright v. Ford Motor Co.*, 508 F.3d 263, 272-74 (5th Cir. 2007) (noting that "establish" means "something more than simply introducing *some* evidence" and finding that a presumption similar to § 82.007 was a Morgan-type presumption that "shift[s] the burden of persuasion and [does] not disappear"); *Ledbetter v. Merck & Co., Inc.*, Nos. 2005-59499, 2005-58543, 2007 WL 1181991, at *3 (157th Dist. Ct., Harris County, Tex. Apr. 19, 2007) (plaintiffs have the burden to "establish" or "prove" exceptions to statute); *Ebel v. Eli Lilly & Co.*, 536 F. Supp. 2d 767, 776 (S.D. Tex. 2008) (plaintiff must "establish" exceptions to § 82.007), *aff'd on other grounds*, 321 F. App'x 350 (5th Cir. 2009) (per curiam).

2. **Exception (1) Does Not Apply.**

Section 82.007(b)(1) allows a plaintiff to rebut the presumption of non-liability with evidence that the defendant withheld or misrepresented information to the FDA during the approval process for the product. Exception (1) does not apply for two independent reasons. First, as a legal matter, federal law preempts reliance on exception (1). Second, as a factual matter, and as plaintiffs' experts have admitted and other courts have held, there is no evidence that Wyeth defrauded the FDA.

a. Exception (1) is Preempted.

In *Lofton v. McNeil Consumer & Specialty Pharm.*, The Honorable Sam Lindsay of the United States District Court for the Northern District of Texas held that the fraud-on-the-FDA exception to § 82.007's presumption is preempted when a plaintiff "ask[s] the court to reach the conclusion opposite of that reached by the FDA . . . ." *Lofton*, 682 F. Supp. 2d at 675-76. As a result, Judge Lindsay granted summary judgment for the defendant when there was no evidence to rebut the statutory presumption of non-liability. On February 22, 2012, the Fifth Circuit Court of Appeals affirmed Judge Lindsay's grant of summary judgment, specifically stating that "the district court correctly found that federal law preempts a Texas tort reform law that requires plaintiffs to assert, in failure to warn cases, that a drug manufacturer withheld or misrepresented material information to the FDA." **Exhibit 1** – *Lofton* Opinion at p. 1-2.

In *Lofton*, the Fifth Circuit held that the fraud-on-the-FDA exception is subject to the Supreme Court's analysis in *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001), which recognized that the FDA has exclusive responsibility to "police fraud consistently with the Administration's

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[57] Three of the exceptions are inapplicable on their face. Exception (2) is inapplicable because the FDA has never withdrawn its approval of Premphase or Prempro or ordered that they be removed from the market; all are still FDA-approved. Exception (4) is inapplicable because it applies only to prescribers, not manufacturers or distributors like the subject defendants. And exception (5), which concerns bribery of public officials and witnesses, 18 U.S.C. § 201, is plainly inapplicable. This leaves exceptions (1) and (3).

judgment and objectives." *Id.* at 350. Relying on *Buckman*, the Fifth Circuit concluded "that federal law dictates which information the manufacturer is obligated to disclose and imposes penalties for omissions and misrepresentations," and therefore, "disclosures to the FDA are 'uniquely federal' and thus beyond the states' traditional police power." **Exhibit 1** – *Lofton* Opinion at p. 12. Because the exception to the presumption of non-liability requires a plaintiff to prove fraud on the FDA, it "invokes federal law supremacy according to *Buckman*." *Id.* at p. 13. By requiring a plaintiff to "establish" a violation of the FDA's required disclosures, the exception necessarily requires a plaintiff to "re-tread[] the FDA's administrative ground both to conduct discovery and to persuade a jury." *Id.* at p. 14-15.

In addition, the Fifth Circuit specifically found that the same policy implications discussed in *Buckman* were raised by the statutory fraud-on-the-FDA exception. For example, a manufacturer's disclosures may be deemed appropriate by the FDA, but later be judged as insufficient by a state court jury. *Id.* at p. 15. This "uncertainty compels manufacturers to flood the FDA with information to ensure that they retain the § 82.007(a)(1) presumption of non-liability." *Id.* Flooding the FDA with a deluge of information causes "FDA [to] lose[] control over its ability, based on scientific expertise, to prescribe—and intelligently limit—the scope of disclosures necessary for its work." *Id.* The Fifth Circuit also recognized that the fraud-on-the-FDA exception "may directly invade the agency's processes when close questions of 'withholding' or 'misrepresentation' arise." *Id.*[58]

The Fifth Circuit's decision in *Lofton* is controlling in this case where there is no evidence that the FDA found that Wyeth committed fraud in its submissions related to Premphase or Prempro. Indeed, these prescription drugs remain on the market and continue to be prescribed by doctors every

[58] The Fifth Circuit did address the implications of the Supreme Court's decision in *Wyeth v. Levine*, 555 U.S. 555 (2009). **Exhibit 1** – *Lofton* Opinion at p. 6-9. After careful consideration of both *Buckman* and *Levine*, the Fifth Circuit held that the fraud-on-the-FDA provision was controlled by *Buckman*, and that the *Levine* decision did not foreclose a holding that the fraud-on-the-FDA exception is preempted by federal law unless the FDA finds fraud.

day. Accordingly, the fraud-on-the-FDA exception is preempted in this case and the presumption of non-liability is dispositive of all of Ms. Romero's claims based on an alleged failure to warn. *See also Pliva, Inc. v. Mensing*, 131 S.Ct. 2567, 2578 (2011) (citing *Buckman* and holding that federal drug and medical device laws pre-empted a state tort-law claim based on failure to properly communicate with the FDA); *Baker v. St. Jude Med., S.C., Inc.*, 178 S.W.3d 127, 138-39 (Tex. App.—Houston [1st Dist.] 2005, pet. denied) (applying *Buckman* to bar a state law tort claim predicated on alleged insufficiency of regulatory submissions to the FDA that would have led to an earlier recall of a defective artificial heart valve); *Garcia v. Wyeth-Ayerst Labs.*, 385 F.3d 961, 966 (6th Cir. 2004) (Michigan law that immunizes a drug manufacturer from products liability suits if the drug was approved by the FDA was preempted to the extent that it permitted a state court to determine whether a drug manufacturer committed fraud on the FDA); *Zammit v. Shire US, Inc.*, 415 F. Supp. 2d 760, 768-69 (E.D. Mich. 2006) (where the FDA itself has made no such findings of deficiencies or fraud, Plaintiff cannot invoke the "fraud on the FDA" exception to the immunity enjoyed by Defendant under Michigan's product liability statute); *Duronio v. Merck & Co.*, No. 267003, 2006 WL 1628516, at *5 (Mich. Ct. App. June 13, 2006) ("we agree with [*Garcia's*] holding that the fraud-on-the-FDA exception is preempted by federal law unless the FDA itself determines that it was defrauded").

b. There is No Competent Evidence that Wyeth Withheld Information from the FDA.

In the event this Court finds that *Lofton* does not dispose of Ms. Romero's failure-to-warn claims in their entirety, Ms. Romero still cannot establish that the fraud-on-the-FDA exception applies. There is no competent evidence that Wyeth withheld information from FDA or misrepresented the information submitted to FDA – certainly not (i) information that Wyeth was required by law to submit and (ii) that would have changed FDA's decision, as Texas law requires. There is nothing in the reports of Ms. Romero's own expert, Dr. Parisian that supports any conclusion that Wyeth withheld

information from the FDA. Indeed, Dr. Parisian herself has testified – and other courts have relied on her testimony[59] – that Wyeth did ***not*** conceal or withhold safety information about its medications from the FDA.[60]

Notably, in HT litigation in New Jersey, the court addressed a motion for summary judgment based on a similar statutory presumption of adequacy. Although the plaintiffs contended that Wyeth concealed or withheld information regarding breast cancer from FDA, the court rejected that argument. *Bailey v. Wyeth, Inc.*, No. MID-L-0999-06 MT, 2008 N.J. Super. Unpub. Lexis 3004, at *57-58 (N.J. Law. Div. July 11, 2008), *aff'd sub nom. DeBoard v. Wyeth, Inc.*, No. A-6230-07T1, 2011 N.J. Super. Lexis 177 (N.J. App. Div. Sept. 29, 2011). In doing so, the court specifically relied on Dr. Parisian's admission that Wyeth did not withhold breast cancer risk information from FDA, stating that "[i]n fact, plaintiffs' expert, Dr. Parisian . . . admitted that the studies at the time on the potential risk were "confusing."[61] Dr. Parisian has further testified in other cases that the label accurately reflected the science at the time.[62]

In finding that there was no evidence of concealment or nondisclosure, the *Bailey* court quoted Dr. Parisian's response to the question of whether Wyeth withheld information from the FDA, to which she answered, "No. And as you know, I've never said that in my report."[63] The *Bailey* court found

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59 **Exhibit 2** - *Bailey* Opinion, at *17; **Exhibit 3** - Letter Opinion, *DeBoard v. Wyeth, Inc.*, No. MID-L-1147-06 MT (N.J. Super. Ct., Middlesex County July 11, 2008) at 2. The New Jersey Appellate Division recently affirmed both orders in a summary opinion that called the trial court's opinion "well-considered and exhaustive." **Exhibit 4** - *DeBoard v. Wyeth, Inc.*, Nos. A-6230-07T1, A-6251-07T1, 2011 N.J. Super. Lexis 177, at *4 (N.J. App. Div. Sept 29, 2011).

60 *See* **Exhibit 11** - Feb. 13, 2008 Trial Transcript, *Scroggin v. Wyeth*, MDL Docket No. 4:03-cv-1507-wrw, at 1510:2-8 (E.D. Ark.); **Exhibit 12** - Nov. 19, 2010 Trial Transcript, *Torkie-Tork v. Wyeth*, Cause No. 1:04-cv-945, at 144:24-145:14 (E.D. Va.); **Exhibit 13** - Nov. 23, 2010 Trial Transcript, *Torkie-Tork v. Wyeth*, Cause No. 1:04-cv-945, at 161:4-162:2 (E.D. Va.).

61 **Exhibit 2** - *Bailey* Opinion, at *17.

62 **Exhibit 11** - Feb. 13, 2008 Trial Transcript, *Scroggin v. Wyeth*, MDL Docket No. 4:03-CV-1507-WRW, at 1510-11, 1514-15 (emphasis added).

63 **Exhibit 2** - *Bailey* Opinion, at *17.

that there was no evidence that the defendants ever intentionally withheld any risk information from the FDA.[64] The same lack of evidence is present in this case, and therefore, Ms. Romero cannot show that Exception (1) applies.

There is also no evidence that anything allegedly "withheld" from the FDA was material. The FDA was presented with numerous studies regarding the risk of breast cancer and the label provided that there were some studies that showed a risk and some studies that did not. Thus, any additional studies showing a risk (or not) are not material and would not have changed the information contain in the label. Additionally, any publicly-available information or studies that did not contain statistically significant results or that were underpowered or contained flawed methodology would also not be material to the FDA's decision.

3. **Exception (3) Does Not Apply.**

An additional exception is found in § 82.007(b)(3), which requires proof that Wyeth promoted its HT medicines for an off-label use, that the plaintiff's doctors prescribed the drugs for an unapproved indication as a result of off-label marketing, ***and*** that the claimant was injured as a result of the off-label prescribing. But the evidence in this case establishes that Ms. Romero was prescribed HT for the treatment of her menopausal symptoms, an ***approved*** indication.[65] There is simply no evidence of any off-label prescription or use, and, therefore, there is no evidence bringing into play exception (3) to the statutory presumption. *See Ebel*, 536 F. Supp. 2d. at 777 (§ 82.007(b)(3) not satisfied absent evidence that off-label promotion reached and influenced the prescribing physician); *see also Holland v. Hoffmann-La Roche*, No. 3-06-CV-1298-BD, 2007 WL 4042757, at *3 (N.D. Tex. Nov. 15, 2007) (holding that, though physician prescribed prescription medicine for an off-label indication, § 82.007(b)(3) was inapplicable because there was no evidence that manufacturer defendant

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64 *Id.*

65 **Exhibit 24** - Lal Dep. at 109:7-20; **Exhibit 22** - Romero Dep. at 159:13-16.

recommended, promoted, or advertised the product for an off-label indication); *see also* Memorandum and Order, *Lea v. Wyeth LLC et al.*, No. 1:03-c-01339-mac, Dkt. No. 173 at 19-20 (finding that the plaintiff was not prescribed HT for any off-label benefit and that she could not rely on the overpromotion exception as a matter of law).

Because there is no genuine issue of material fact as to any of the exceptions to the presumption of non-liability, the presumption applies and Wyeth is entitled to summary judgment on all of Ms. Romero's failure-to-warn claims, regardless of the legal theory under which a particular claim is pleaded.

4. **Ms. Romero Cannot Present Reliable Expert Evidence that the Warning Was Inadequate.**

An independent ground exists warranting summary judgment for Wyeth on Ms. Romero's failure-to-warn claims. If the Court excludes the failure-to-test opinions of Ms. Romero's regulatory experts, Drs. Suzanne Parisian, Cheryl Blume and Bruce Patsner, there will be no evidence to support a failure to warn.[66]

Under Ms. Romero's theory of the case, she must prove that Wyeth's testing of HT was inadequate in order to demonstrate that the HT breast cancer warnings were inadequate. This is so because Ms. Romero's own evidence establishes that the pre-WHI breast cancer warning was accurate based on prevailing scientific knowledge. Dr. Parisian has testified that the pre-WHI Prempro label "***is not false***."[67] Ms. Romero's general causation expert, Dr. Graham Colditz, has testified that in the mid-1990s "most studies" showed no relation between HT and breast cancer, although other studies showed

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[66] *See* Defendants' Motion to Exclude the Testimony of Drs. Parisian, Blume, and Patsner and Brief in Support, filed contemporaneously with this Motion.

[67] **Exhibit 11** - Feb. 13, 2008 Trial Transcript, *Scroggin v. Wyeth*, MDL Docket No. 4:03-CV-1507-WRW, at 1510-11, 1514-15 (emphasis added).

an "increased incidence in breast cancer in women who had taken estrogen replacement therapy."[68] The subject HT labeling was consistent with the data. For example, the original Prempro label, as approved by the FDA in December 1994, reported in the WARNINGS section:

> Some studies have reported a moderately increased risk of breast cancer (relative risk of 1.3 to 2.0) in those women on estrogen replacement therapy taking higher doses . . . . The majority of studies, however, have not shown an association [with breast cancer] in women who have ever used estrogen replacement therapy.[69]

This label is also consistent with the ultimate results from the WHI, which identified a relative risk of 1.24.[70]

Ms. Romero's claim that the breast cancer warning was inadequate despite being consistent with scientific knowledge at the time is predicated on the allegation that Wyeth failed to test as a "reasonable" company would have. Ms. Romero cannot prevail on her failure-to-warn claims without expert testimony that Wyeth failed to do what a "reasonable" company should have done to further test the association between HT and breast cancer. If the Court grants Wyeth's motion to exclude these opinions of Ms. Romero's experts, as Magistrate Judge Hawthorn did in another HT case, summary judgment will be warranted for this additional reason.

B. Ms. Romero Cannot Establish a Design Defect Claim.

Ms. Romero also advances claims for design defect and negligent design, but she has no viable claim in light of Section 402A of the *Restatement (Second) of Torts*. Nor is there any evidence of an alternative safer design. Consequently, Wyeth is entitled to summary judgment on Ms. Romero's design defect and negligent design claims.

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68 *See* **Exhibit 14** - Deposition of Dr. Graham Colditz (Dec. 18, 2006) at 251-54; **Exhibit 15** - Deposition of Dr. Graham Colditz (May 2, 2006) at 361-62.

69 **Exhibit 16** - Physicians' Desk Reference – Prempro (1996), at 2803.

70 **Exhibit 9** - Chlebowski 2003 at 3243.

1. Ms. Romero Does Not Have a Viable Design Defect Claim Under Section 402A of the *Restatement (Second) of Torts*.

In general, a product is defectively designed under Section 402A if it is unreasonably dangerous taking into consideration its utility and the risks involved in its use. *American Tobacco Co., Inc. v. Grinnell*, 951 S.W.2d 420, 432 (Tex. 1997). Prescription medicines, however, present a unique issue. By their nature, such medicines may cause significant adverse events; yet, they also can bring significant benefits when properly used. It is for that reason that they are only available by prescription from a licensed healthcare provider:

> Prescription drugs are likely to be complex medicines, esoteric in formula and varied in effect. As a medical expert, the prescribing physician can take into account the propensities of the drug, as well as the susceptibilities of his patient. His is the task of weighing the benefits of any medication against its potential dangers.

Wyeth-Ayerst Labs. Co. v. Medrano, 28 S.W.3d 87, 91 (Tex. App.—Texarkana 2000, no pet.) (quoting *Reyes v. Wyeth Labs.*, 498 F.2d 1264, 1276 (5th Cir. 1974)).

Comment k to section 402A recognizes that "[t]here are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use." *Restatement (Second) of Torts* § 402A, cmt. k. Prescription medicines fall into this category because no medicine that has a therapeutic benefit is risk-free. *See id.* (noting that some drugs "for this very reason cannot legally be sold except to physicians, or under the prescription of a physician"). For this reason, Wyeth respectfully maintains that the only viable claims against a prescription drug maker are for a manufacturing defect (*i.e.*, contamination or misformulation) or a marketing defect (*i.e.*, failure to warn or inadequate warning). *See Hackett v. G.D. Searle & Co.*, 246 F. Supp. 2d 591, 595 (W.D. Tex. 2002) ("The Court thus holds that under Texas law and comment k of the Restatement, Defendants can only be held strictly liable if the drug was not properly prepared or marketed or accompanied by proper warnings."). It is undisputed that Prempro and Premphase are prescription medicines. Accordingly,

Wyeth is entitled to summary judgment on Ms. Romero's negligent design and design defect claims under comment k to Section 402A.

2. Ms. Romero Does Not Have Competent Evidence of a Safer Alternative Design, Which is a Requisite of Any Design Defect Claim.

In any event, Ms. Romero has no competent evidence of a safer alternative design. In order to prove a design defect claim, Texas courts applying Section 402A require a plaintiff to demonstrate that the defendant could have provided a safer alternative design. *See Guzman v. Synthes (USA)*, 20 S.W.3d 717, 721-22 (Tex. App.—San Antonio 1999, pet. denied) (affirming grant of motion for summary judgment under Texas common law because the evidence was legally insufficient to establish a safer alternative design for a medical device); *see also Gerber v. Hoffmann-La Roche Inc.*, 392 F. Supp. 2d 907, 922 (S.D. Tex. 2005) (summary judgment in prescription drug case where plaintiff offered no evidence of a safer alternative design).[71] Ms. Romero has no competent evidence of a safer alternative design, and on that additional ground her claims fail.

To establish a safer alternative design, Ms. Romero must establish at least three things: 1) that the purported alternative design was feasible at the time she was taking the product; 2) that the alternative design would have been prescribed by her doctor and would have been effective in treating her symptoms; and 3) that the alternative design would have somehow prevented her breast cancer. Ms. Romero's experts advance the argument that estrogen + oral micronized progesterone (E+OMP) is a safer alternative design to estrogen + medroxyprogesterone acetate (E+MPA). But this argument fails as a matter of law for the reasons stated in Wyeth's Motion to Exclude the Testimony of Drs.

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[71] For products other than drugs or medical devices, the safer alternative design requirement is codified. TEX. CIV. PRAC. & REM. CODE ANN. § 82.005 (Vernon 2011). But the same basic requirement applies to drugs and medical devices under Texas common law. *See Guzman*, 20 S.W.3d at 721; *Gerber*, 392 F. Supp. 2d at 922; *see also Dyer v. Danek Med., Inc.*, 115 F. Supp. 2d 732, 738 (N.D. Tex. 2000) (requiring proof of safer alternative design in medical device case in which Texas law was controlling). A Texas court of appeals recently applied this common law safer alternative design requirement in a

Austin and Tilley, which is being filed contemporaneously with this Motion. United State Magistrate Judge Zack Hawthorn agreed that such opinions by Drs. Austin and Tilley are unreliable and inadmissible in another HT case,[72] and for the same reasons, they should also be inadmissible in this case.

Similarly, any argument that lower dose Prempro is a safer alternative design also fails. Wyeth notes at the outset that Ms. Romero's First Amended Petition does not discuss lower dose Prempro as a safer alternative design, and she has not identified any expert witnesses who will offer this opinion. Thus, Ms. Romero should not be able to advance this argument at the summary-judgment stage. Even if she could properly assert this argument, any contention that lower dose Prempro is a safer alternative design still fails for several reasons.

First, there is no competent evidence that lower dose Prempro was feasible at the time Ms. Romero took HT. FDA did not approve what is now called low-dose Prempro until 2003. The expert reports are silent as to whether Wyeth could have done the studies necessary to secure FDA approval earlier. Second, while we can assume that Ms. Romero's doctors would have prescribed a low dose of Prempro for her to begin with (because the labeling recommends that doctors prescribe the lowest effective dose), Ms. Romero has not presented any expert evidence that low-dose Prempro would have been effective in treating her symptoms. After all, the full range of doses are approved as safe and affective precisely because the lowest dose does not work for everyone. In fact, Ms. Romero continued to have symptoms even while she was taking the higher dose of HT.[73] Third, no expert for Ms. Romero has opined that had she taken some lower dose of HT, she would not have developed breast

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Prempro case. *Brockert v. Wyeth Pharm., Inc.*, 287 S.W.3d 760, 769-71 (Tex. App.—Houston [14th Dist.] 2009, no pet.).

[72] Order Granting in Part and Denying in Part Defendants' Motion to Exclude the Testimony of Drs. Tilley and Austin, *Lea v. Wyeth LLC et al.*, Cause No. 1:03-cv-01339-mac, Dkt. No. 130 (attached as Exhibit 6 to Wyeth's Motion to Exclude Drs. Austin and Tilley [Dkt. No. 85-8]).

cancer. In prior HT trials, plaintiffs' experts have conceded that there is no scientific data to support the claim that one dose of Prempro is safer than another in terms of breast cancer risk; both products are accompanied by the same breast cancer warning.[74] Therefore, Wyeth is entitled to summary judgment on the design defect and negligent design claims.

These issues illustrate why design defect claims are problematic and disfavored when applied to prescription medicines. The concept of a safer alternative design may be reasonable in a variety of contexts – one can imagine, for instance, the addition of safety features to a table saw or a disposable lighter because those additions would not fundamentally alter the devices' characteristics or impair their utility. Changing the chemical composition or dosage of a drug does not change the drug's design, however; it turns it into a different drug, with its own unique risks and benefits. Thus, in the context of prescription drugs, unlike other contexts, any proposed "safer" alternatives may actually result in uncertainty or risk.

Nor will evidence of alternative medical treatments that were available to the doctor, including different drugs, satisfy the safer alternative design requirement. In a 1999 case construing Louisiana law, which has a similar alternative design requirement, the Fifth Circuit held that the plaintiff could not defeat summary judgment in a pedicle screw case with evidence of alternative treatments:

> Theriot claims that the product at issue here is a product whose purpose is to provide biomechanical stability. Theriot therefore argues that other products that do not use pedicle screws should be considered as alternative designs, such as external neck braces or internal systems that use hooks or wires. Underlying this argument is the assumption that all pedicle screws are defective and there can be no system using pedicle screws that would be an acceptable product. The problem with this argument is that it really takes issue with the choice of treatment made by Theriot's physician, not with a specific fault of the pedicle screw sold by Danek.

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[73] *See supra* note 23.

[74] *See supra* notes 47-53 and accompanying text (discussing the warnings that accompany Premphase and Prempro).

Theriot v. Danek Med., Inc., 168 F.3d 253, 255 (5th Cir. 1999) (per curiam); *see also Dyer v. Danek Med., Inc.*, 115 F. Supp. 2d 732, 738-39 (N.D. Tex. 2000) (relying on *Theriot* in a pedicle screw case governed by Texas law and granting summary judgment for manufacturer on the grounds that plaintiff failed to identify a safer alternative design and that any ostensible alternative that did not use pedicle screws was not an alternative design). Thus, under *Theriot* any argument that "alternative treatments" on the market today are safer alternative designs sufficient to establish a design defect fails as a matter of law.

More recently, a Texas appellate court issued a similar ruling with respect to Prempro. In *Brockert v. Wyeth Pharmaceuticals, Inc.*, the trial court granted Wyeth summary judgment on the plaintiff's design defect claim. 287 S.W.3d at 763, 769. On appeal, the dispositive issue was whether the plaintiff had come forward with any competent evidence of a safer alternative design.[75] *See id.* at 769-71. The plaintiff contended that she had presented substantial evidence of a safer alternative design, urging that "the safer alternative design to estrogen in combination with progestin is estrogen alone" and submitted expert testimony to this effect. *Id.* at 769-70. Wyeth argued in response that this was not an alternative design of Prempro but rather a different drug altogether. *Id.* at 769. The court agreed with Wyeth:

> [A] safer alternative design must be one for the product at issue—here, Prempro. As [plaintiff's expert] Dr. Lehane points out in his affidavit, in prescription drugs like Prempro, "synthetic progestin was added to estrogen to reduce the incidence of endometrial hyperplasia." But Brockert does not explain how Prempro could have been modified or improved; she instead argues that progestin should not have been added to estrogen. In essence, Brockert argues that the product Prempro should have

[75] Because the appellate court determined that the plaintiff had failed to adduce any competent evidence of a safer design, it did not address the defendant's alternative argument that comment k of Section 402A exempts prescription drugs from design defect claims. 287 S.W.3d at 769. The appellate court also reversed the grant of summary judgment on the plaintiff's failure-to-warn claim and remanded that claim back for trial. 287 S.W.3d at 762, 771. Wyeth maintains that its summary judgment should have been affirmed on all grounds.

> been a different product: its predecessor Premarin. But, as the Supreme Court has explained, Texas law does not recognize this sort of categorical attack on a product.

Brockert, 287 S.W.3d at 770-71.

Because Ms. Romero has no expert testimony regarding the existence of a safer alternative design that would have eliminated the allegedly increased risk of breast cancer and yet provided the same beneficial effect, the Court should grant summary judgment on her design defect and negligent design claims on this independent ground as well.

C. Plaintiff has No Basis for Recovery of Exemplary Damages.

Finally, there is no evidence to support Ms. Romero's claim for exemplary damages under the applicable provisions of Chapter 41 of the Texas Civil Practice and Remedies Code. Under Section 41.003(a), "[E]xemplary damages may be awarded only if the claimant proves by clear and convincing evidence that the harm with respect to which the claimant seeks recovery of exemplary damages results from fraud, malice, or gross negligence." TEX. CIV. PRAC. & REM. CODE ANN. § 41.003(a) (Vernon 2011).

For purposes of exemplary damages, "malice" is defined as "a specific intent by the defendant to cause substantial injury or harm to the claimant." *Id.* § 41.001(7). Gross negligence is an act or omission:

> (A) which when viewed objectively from the standpoint of the actor at the time of its occurrence involves an extreme degree of risk, considering the probability and magnitude of the potential harm to others; and
>
> (B) of which the actor has actual, subjective awareness of the risk involved, but nevertheless proceeds with conscious indifference to the rights, safety, or welfare of others.

Id. § 41.001(11).

Finally, "fraud" is defined as "fraud other than constructive fraud." *Id.* § 41.001(6) Ms. Romero has no evidence, much less evidence under the clear and convincing evidence standard, that Wyeth acted with the requisite level of intent under any of these theories to cause injury to Ms. Romero. In

fact, as discussed above, the FDA convened an independent advisory committee prior to the approval of Prempro and that committee found the information regarding breast cancer to be inconclusive.[76] The Premphase and Prempro labels were consistent with that conclusion. Consequently, as a matter of law, Ms. Romero is not entitled to exemplary damages and summary judgment is appropriate on that damages measure.

VI. CONCLUSION

For the foregoing reasons, Wyeth is entitled to summary judgment on Ms. Romero's claims based on an alleged failure to warn and her claims of strict liability: design defect and negligent design, and Ms. Romero is not entitled to punitive damages. Wyeth prays that judgment be entered in its favor and that it be awarded any other relief to which it has shown itself justly entitled.

Dated: February 24, 2012

Respectfully Submitted,

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[76] *See supra* notes 7-11 and accompanying text.

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CERTIFICATE OF SERVICE

I hereby certify that on this 24th day of February, 2012 a true and correct copy of the foregoing was filed with the Court and served via electronic notification on all counsel of record.

/s/ Janelle L. Davis
Janelle L. Davis

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